SUBSTANTIAL EQUIVALENCE OPINION

Vitamin K_2

The Food Safety Authority of Ireland (FSAI) received an application in March of 2015 from Vesta Ingredients Inc. of Indianapolis in the USA for an opinion on the substantial equivalence of its vitamin K_2 oil (MK-7) 1,500 ppm to the same ingredient previously authorised to NattoPharma by Commission Decision 2009/345/EC. The NattoPharma vitamin K_2 is produced by fermentation with *Bacillus subtilis*, subspecies *natto* which is then extracted, purified and presented as an oil suspension. The vitamin K_2 from Vesta Ingredients is also produced by fermentation with *Bacillus subtilis*, subspecies *natto* which is then extracted, purified and presented as an oil suspension. Commission Decision 2009/345/EC stipulates that the novel ingredient is designated as "Menaquinone" or "Vitamin K" and that menaquinone-7 (MK-7) is the primary constituent, with menaquinone-6 (MK-6) present to a smaller but undefined extent. The applicant considers the ingredient to be novel within the category of "foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae" as stipulated in *Article 1.2(d)* of the novel food Regulation EC No. 258/97.

Composition

The novel ingredient is presented in an oil formulation containing at least 0.15% (1,500 ppm) of total vitamin K_2. The applicant provides data demonstrating that the vitamin K_2 is made up primarily of Menaquinone7 (MK-7) and contains trace levels of Menaquinone6 (MK-6). The oil used as a formulation aid is different to the comparator (sunflower oil) and is a food grade mixture of glycerol from vegetable oils and medium-chain fatty acids from coconut and palm oils which primarily accounts for the fat and mineral content of the final product, while no carbohydrate or protein is present. The specifications for the novel and authorised ingredients provided are almost identical and include total and specific vitamin K_2 content as well as its appearance as free flowing yellow to yellow-brown coloured oil with a mild aroma or flavour. Also provided are data comparing the levels of undesirable substances such as heavy metals and microbial contaminants. The novel vitamin K_2 is produced by fermentation with *Bacillus subtilis*, subspecies *natto*, extracted with ethanol prior to drying and resuspended in coconut and palm oil. The applicant recommends that the

vitamin K2 oil is stored in the original unopened containers with controlled handling temperatures (≤ 32°C), light and humidity.

Nutritional Value and Metabolism

The composition of the vitamin K_2 containing oil from both sources is very similar and so it is reasonable to assume that the nutritional value and metabolism will also be equivalent. The novel ingredient is presented in an oil suspension (vegetable glycerol, coconut oil and palm oil) which primarily accounts for the fat and mineral content and is of similar nutritional value to the authorised ingredient which uses sunflower oil. The applicant has determined that the vitamin K_2 is stable under accelerated conditions for up to 90 days, which is calculated as equivalent to 2 years of shelf life.

Intended Uses

The applicant intends to use the novel ingredient for the same purposes as the authorised ingredient and in compliance with Directive 2001/15/EC relating to substances that may be added for specific nutritional purposes in foods for particular nutritional uses and with Regulation EC No. 1925/2006 on the addition of vitamins, minerals and certain other substances to foods.

Level of Undesirable Substances

The production, extraction and purification process ensures a high grade oily vitamin K_2 product with the ingredient specification and batch analysis provided by the applicant demonstrating equivalence to the authorised ingredient. The applicant provides data on the levels of heavy metals, microbiological content and mycotoxins in the final ingredient as well as data from a number of oral toxicity studies in animals that did not identify any potential health concerns. Ethanol is used in the extraction process but is not detectable in the final ingredient, while protein is also absent from the final ingredient providing reassurance on potential allergenicity concerns.

Conclusions

The FSAI is satisfied from the information provided by the applicant that vitamin K_2 produced by Vesta Ingredients Inc. is substantially equivalent to vitamin K_2 authorised for marketing by Commission Decision 2009/345/EC. The novel vitamin K_2 will be designated as “Menaquinone” or “Vitamin K”, as stipulated in Commission Decision 2009/345/EC.